

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.:	07/ 978,891	Group Art Unit:	1644
Confirmation No.:	4493	Examiner:	R.B. Schwadron
Filed:	13 November 1992		
Applicant:	Darrell R. ANDERSON <i>et al.</i>		
For:	Therapeutic Application of Chimeric and Radiolabeled Antibodies to Human B Lymphocyte Restricted Differentiation Antigen for Treatment of B Cell Lymphoma		

Mail Stop **Petition**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**PETITION UNDER 37 C.F.R. § 1.137(b) TO REVIVE
AN UNINTENTIONALLY ABANDONED APPLICATION FOR COPENDENCY**

Sir:

In connection with the recent evaluation of a petition in a pending application (serial no. 09/911,703) that claims priority to the captioned application, serial no. 07/978,891, it has come to applicant's attention that application serial no. 07/978,891 may have become abandoned through unintentional delay before a continuing application, serial no. 08/149,099, now U.S. Patent No. 5,736,137, was filed. In particular, the '891 application may have become abandoned as early as 16 September 1993, whereas the '099 application was filed as a continuation-in-part of the '891 application on 3 November 1993. The record demonstrates that applicant intended, and the Office proceeded under the assumption, that the '099 application was filed prior to the abandonment of the '891 application. Accordingly, applicant petitions under 37 C.F.R. § 1.137(b) to revive the captioned '891 application solely for the purpose of establishing copendency with the '099 application.

The Director is requested to debit the required petition fee of **\$1,540** (§ 1.17(m)) from our **Deposit Account No. 18-1260**. Any other fee required for entry or consideration of this paper may be charged to the same account.

Facts

1. Application serial no. 07/978,891 was an original application filed on 13 November 1992. The transmittal papers for the application requested the Commissioner to “[p]lease charge any additional fees or credit any overpayment to” the assignee’s deposit account.
2. Following exchanges concerning formalities, the Office mailed a first action on the merits on 15 June 1993 (Paper No. 11). The Office action was nonfinal and set a 3-month period for response. The last day for filing a timely reply without an extension of time was 15 September 1993.
3. Applicant did not file a reply to the first action. Instead, on 3 November 1993, applicant filed application serial no. 08/149,099 as a continuing application claiming priority under 35 U.S.C. § 120 to the '891 application. The transmittal papers for the '099 application, annexed as Attachment A, stated that “[t]his application is a Continuation-in-Part of US Serial Number 07/978,891, filed on November 13, 1993 [sic, 1992] (pending) ...” (emphasis added). Additionally, the first page of the specification of the '099 application as filed, annexed as Attachment B, stated that “[t]his is a Continuation-in-Part of United States Serial No. 07/978,891, filed November 13, 1992, pending” (emphasis added).
4. On 7 December 1993, the examiner of the '891 application contacted applicant by telephone. The examiner’s interview summary (Paper No. 13) stated that “Applicant notified Examiner that case will be abandoned” (emphasis added).
5. On 15 December 1993, applicant’s representative executed and mailed a paper titled “Express Abandonment of Patent Application Under 37 CFR 1.138.” The paper referred to the filing of the continuation-in-part application on 3 November 1993 and stated, “in an effort to focus attention and resources on the CIP, Applicants have opted to abandon the present application in favor of the CIP.” The paper further stated that “an Official Action issued in this case on June 15, 1992; a response thereto will not be filed.” The paper was received by the PTO on 20 December 1993 and entered in the file wrapper as Paper No. 15.

6. On 17 December 1993, the Office mailed a notice of abandonment (Paper No. 14). The examiner indicated that the application was abandoned in view of "Applicant's failure to respond to the Office letter, mailed 6/15/93."
7. The continuation data recorded in the file wrapper of the continuation-in-part application, serial no. 08,149,099, indicates that the Office recognized applicant's claim for priority to the '891 application under § 120. The '099 application was examined by the same examiner, Examiner Schwadron, who was the examiner of record of the '891 application. The '099 application matured to U.S. Patent No. 5,736,137 on 7 April 1998. The face of the '137 patent, annexed as Attachment C, states that the patent is a continuation-in-part of the '891 application.

Discussion

As the facts above demonstrate, applicant believed that the '891 application was pending on 3 November 1993, the date that a continuation-in-part application, serial no. 08/149,099, was filed. Notwithstanding this manifest belief, as well as the blanket fee authorization language included in the filing papers for the '891 application, a review of the official file does not show that an extension of time to respond to the Office action mailed on 15 June 1993 was granted during the pendency of the application. Applicant has not been able to identify evidence from its records that a fee was paid under the blanket authority provided in the filing papers that would correspond to a fee for an extension of time to respond to the Office action mailed 15 June 1993. Accordingly, it appears that the '891 application may in fact have become abandoned on 16 September 1993, before both the date that applicant filed a continuing application as well as the date that applicant filed a letter of express abandonment. Applicant therefore considers that it is prudent to petition the Director to revive the application for the limited purpose of ensuring that the copendency requirement of 35 U.S.C. § 120 is met as to application serial no. 08/149,099.

A petition under 37 C.F.R. § 1.137(b) to revive an application that became abandoned as a result of an unintentional delay by the applicant in submitting a reply requires four elements:

- (1) The reply required to the outstanding Office action, unless previously filed.

- (2) The petition fee required under § 1.17(m).
- (3) A statement that the entire delay in filing the required reply, up to the date of filing a grantable petition, was unintentional.
- (4) Any terminal disclaimer as required under § 1.137(d).

(1) *Reply*

The continuing application filed on 3 November 1993 constitutes a reply to the outstanding Office action within the meaning of § 1.137(b)(1). See M.P.E.P. § 711.03(c), subsection II.A.

(2) *Fee*

Payment of the required fee by debit from our deposit account is requested on the first page of this petition. The fee will be tendered electronically when this petition is filed via EFS-web.

(3) *Unintentional delay*

The undersigned states, on information and belief following reasonable inquiry of the assignee, that the entire delay from the due date for the reply to the Office action mailed on 15 June 1993 until the filing of the present petition was unintentional.

The Manual identifies three intervals of delay that are relevant to consideration of a petition under § 1.137. See M.P.E.P. § 711.03(c), subsection II.D.

(A) *Delay in the reply that originally resulted in the abandonment.* This first period of delay corresponds to time from the end of the original, unextended period for response to the first Office action, 15 September 1993, until the date the continuation-in-part application was filed, 3 November 1993. The record amply and unambiguously documents that it was applicant's affirmative intention to maintain the pendency of the '891 application during that interval:

- The filing papers for the '099 application clearly stated that the '891 application was believed to be "pending."

- The prosecution of the '099 application (now U.S. Patent No. 5,736,137) demonstrates applicant's intention and expectation that the claim under § 120 for benefit of the '891 application would be effective.
- The interview summary dated 7 December 1993 (Paper No. 13) records applicant's representation that the application "will be abandoned" (i.e., sometime after 7 December 1993). This fact reflects applicant's belief that the '891 application was pending on 7 December 1993.
- The paper titled "Express Abandonment" (Paper No. 15), executed on 15 December and filed on 20 December 1993, manifests applicant's intention to abandon the application as of the date the paper was executed, and no sooner. This fact reflects applicant's belief that the '891 application was pending on 15 December 1993.

(B) Delay in filing an initial petition to revive the application. During the interval from 1993 to 2007, neither the assignee of this application nor its representatives were aware that the original '891 application and the CIP '099 application may not have been copending. The record clearly reflects that applicant believed in the first instance that the pendency of the '891 application had been maintained at least until the filing of the '099 application. Applicant stated a claim for priority to the '891 application in several subsequent applications, including those that matured to U.S. Patent Nos. 5,736,137, 5,776,456, 5,843,439, 6,399,061, and 6,682,734, as well as pending application serial nos. 09/911,692, 09/911,703, and 10/238,681. In every case, the Office recognized applicant's claim for priority and treated it as proper. Moreover, every U.S. application claiming priority to the original '891 application has been examined by the same examiner. When prior art has been applied, no question regarding applicant's ability properly to claim priority to the '891 application has been raised. The compliance with the requirements of § 120 of the claim for priority to the original application – which, it was understood, had indeed been abandoned after the '099 CIP application was filed – has never been questioned throughout the examination of these related applications.

Applicant's representatives first became aware in late October, 2007, that the '891 application may have become abandoned before the '099 application was filed. On 29 March 2007, applicant filed a petition under § 1.78(a)(3) to accept a delayed priority claim in

pending application serial no. 09/911,703, which claims priority to the '891 application. (The '703 application was filed in July 2001; an amendment to conform the priority claim in the specification of the '703 application with the formal requirements of § 120 was filed in August 2005; and the examiner advised applicant in an Office action mailed on 29 December 2006 that a petition under § 1.78(a)(3) would be required.) Between April and October of 2007, applicant repeatedly contacted the Office of Petitions to inquire about the status of the petition. In discussions that occurred with personnel in that office in late October and early November, 2007, applicant was advised that a question had arisen concerning the formal sufficiency of the priority claim as to the '891 application. In particular, applicant was informed that the '891 application may not have been pending on the date that the '099 application was filed.

Upon becoming aware of the possibility that the '891 and '099 applications may not have been copending, the undersigned immediately obtained and reviewed a copy of the public record for the '891 application file. Applicant also diligently began a search of its records, including records related to the deposit account identified in the filing papers for the '891 and '099 applications. Applicant is continuing to search these records. Nonetheless, based on discussions with various Office personnel, and to remove the issue from any doubt, applicant and its representatives determined that a petition to revive the '891 application should be filed, and this petition was promptly prepared. Accordingly, no part of the delay between the filing of the '099 application in November 1993 and the filing of the present petition was intentional.

(C) Delay between the filing of an initial petition and a grantable petition under § 1.137. Applicant believes that the present petition complies with the requirements of § 1.137, as explained at M.P.E.P. § 711.03(c), and is therefore grantable as filed.

(4) Terminal disclaimer pursuant to § 1.137(d)

This application was filed before 8 June 1995, and this petition is not filed solely for purposes of copendency with an application filed on or after 8 June 1995. Accordingly, this petition is subject to the requirements of § 1.137(d)(1).

This petition is submitted with a concurrently-filed petition under § 1.183 to waive the terminal disclaimer requirement of § 1.137(b)(4), as discussed at M.P.E.P. § 711.03(c), subsection II.G.

Conclusion

Applicant respectfully requests that application serial no. 07/978,891 be revived solely to establish copendency with application serial no. 08/149,099, filed on 3 November 1993, and that once such copendency has been established, the application again be abandoned.

Respectfully submitted,

/David L. Fitzgerald/

David L. Fitzgerald, Reg. No. 47,347
Attorney for Biogen Idec Inc.

7 November 2007

SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, DC 20005

tel. (202) 736-8818
fax (202) 736-8711

ATTACHMENT A



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Date: 3 November 1993

PATENT APPLICATION TRANSMITTAL LETTER

HONORABLE COMMISSIONER OF PATENTS
AND TRADEMARKS
Box SEQUENCE
Washington D.C. 20231

Transmitted herewith for filing by:

a. EXPRESS MAIL
 b. Hand Delivery

is the

a. complete
 b. incomplete

Patent Application of: ANDERSON, DR; HANNA, N; LEONARD, JE; NEWMAN, RA; REFF, ME; RASTETTER, WH.

Title: THERAPEUTIC APPLICATION OF CHIMERIC AND RADIOLABELED ANTIBODIES TO HUMAN LYMPHOCYTE RESTRICTED DIFFERENTIATION ANTIGEN FOR TREATMENT OF B CELL LYMPHOMA

Executed On: 3 November 1993

This Application is a Continuation-In-Part of US Serial Number 07/978,891, filed on November 13, 1993 (pending) and priority under 35 U.S.C. §120 is hereby claimed.

1. An application consisting of 80 pages of specification and claims and 21 sheets of formal/informal drawings is attached.

2a. A Declaration and Power of Attorney is attached.

2b. A Declaration and Power of Attorney is not attached. Please file this application in the name of the inventors listed above (full names of all).

3. An assignment of the invention to IDEC Pharmaceuticals Corporation will follow.

4. A filing date in accordance with 37 C.F.R. 1.10 is requested. The Express Mail Certificate appears below.

5. A Small Entity Form is attached.

3
COMPUTATION OF FEE

	Number Filed		Number Extra	Rate	Basic Fee
Total					\$710/\$355
Claims	20	-20=	0	x \$22/\$11=	0
Independent					
Claims	5	-3=	2	x \$74/\$37=	\$74
Multiple					
Dependent					
Claims	0			x \$230/\$115=	0
Total Filing Fee					\$429
Assignment Recording Fee (\$8.00)					\$
TOTAL					\$429

 6. Our check no. _____ in the amount of \$_____ to cover the total fee as computed above is enclosed.

 7. No fee is enclosed.

X 8. Please charge any fees, including those listed in **TOTAL** above, or credit any overpayment to Deposit Account no. 09-0017. A copy of this sheet is enclosed.

Respectfully submitted,



Richard P. Burgoon, Jr.

Reg. No. 34,787

Intellectual Property Counsel

IDECH PHARMACEUTICALS CORPORATION

11011 Torreyana Road

San Diego, CA 92121

(619) 550-8500

EXPRESS MAIL CERTIFICATE

"Express Mail" mailing label number:
Date of deposit:

EF092540446 US MAIL
3 November 1993

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Box SEQUENCE, Washington, D.C. 20231.

Mabel R. Hernandez

(Typed or printed name of person mailing paper or fee)



(Signature of person mailing paper or fee)

ATTACHMENT B

08/149099

21-DUE 23

**THERAPEUTIC APPLICATION OF CHIMERIC AND RADIOLABELED
ANTIBODIES TO HUMAN B LYMPHOCYTE RESTRICTED
DIFFERENTIATION ANTIGEN FOR TREATMENT OF B CELL
LYMPHOMA**



Darrell R. Anderson, Nabil Hanna, John E. Leonard
Roland A. Newman, Mitchell E. Reff and William H. Rastetter

37 C.F.R. §1.74(d)/(e) Copyright Notice

10 A portion of the disclosure of this patent document contains material which is subject to copyright protection. The copyright owner does not object to the reproduction by anyone of the patent document or the patent disclosure, as it appears in the Patent and Trademark Office patent files or records, but otherwise reserves all copyright rights whatsoever.

15

RELATED APPLICATIONS

6/10/92 This is a Continuation-in-Part of United States Serial No. 07/978,891, filed *6/10/92* November 13, 1992, pending. This patent document is related to United States Serial No. 07/977,691, entitled "IMPAIRED DOMINANT SELECTABLE MARKER SEQUENCE FOR ENHANCEMENT OF EXPRESSION OF CO-LINKED GENE PRODUCT AND EXPRESSION VECTOR SYSTEMS" having U.S. Serial No. 07/977,691 (now abandoned) filed November 13, 1992 and "IMPAIRED DOMINANT SELECTABLE MARKER SEQUENCE AND INTRONIC INSERTION STRATEGIES FOR ENHANCEMENT OF EXPRESSION OF GENE PRODUCT AND EXPRESSION VECTOR SYSTEMS COMPRISING SAME," U.S. Serial No. 08/147,696 (filed 6/10/92) (now US Patent 5,648,264) simultaneously herewith. The related patent documents are incorporated herein by reference.

30

6/10/92 This document is being filed in accordance with Rule 10.
EXPRESS MAIL LABEL NO. 1108470285 EFO9751044605
DATE OF DEPOSIT: 6/10/92

ATTACHMENT C



US005736137A

United States Patent [19]

Anderson et al.

[11] Patent Number: 5,736,137
 [45] Date of Patent: Apr. 7, 1998

[54] THERAPEUTIC APPLICATION OF CHIMERIC AND RADIOLABELED ANTIBODIES TO HUMAN B LYMPHOCYTE RESTRICTED DIFFERENTIATION ANTIGEN FOR TREATMENT OF B CELL LYMPHOMA

[75] Inventors: **Darrell R. Anderson**, Escondido; **Nabil Hanna**, Olivenhain; **John E. Leonard**, Encinitas; **Roland A. Newman**, Mitchell E. Reff, both of San Diego; **William H. Rastetter**, Rancho Santa Fe, all of Calif.

[73] Assignee: **Idec Pharmaceuticals Corporation**, San Diego, Calif.

[21] Appl. No.: 149,099

[22] Filed: Nov. 3, 1993

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 978,891, Nov. 13, 1992, abandoned.

[51] Int. Cl. ⁶ A61K 39/395; C07K 16/30; C12N 1/21; C12N 5/20

[52] U.S. Cl. 424/133.1; 424/143.1; 424/144.1; 424/156.1; 424/174.1; 424/800; 424/801; 424/153.1; 435/320.1; 435/328; 435/334; 435/343.1; 435/252.3; 435/70; 435/72; 435/15; 435/104; 530/387.3; 530/388.22; 530/388.73; 530/388.85; 530/867

[58] Field of Search 424/133.1, 143.1, 424/144.1, 156.1, 174.1, 800, 801, 153.1; 435/69.6, 172.3, 252.3, 320.1, 240.2, 328, 334, 343.1; 536/23.4, 23.5, 23.53; 530/387.3, 388.22, 388.73, 388.85, 867; 935/70, 72, 15, 104

[56] References Cited

U.S. PATENT DOCUMENTS

5,500,362 3/1996 Robinson et al. 435/7.23

FOREIGN PATENT DOCUMENTS

125 023 11/1984 European Pat. Off.
 173 494 5/1986 European Pat. Off.
 0 274 394 7/1988 European Pat. Off.
 0451216 B1 10/1991 European Pat. Off.
 0682040 A1 11/1995 European Pat. Off.
 WO 88/04936 7/1988 WIPO.
 WO 92/07466 5/1992 WIPO.

OTHER PUBLICATIONS

"Antibody Shows Promise in Treating B-Cell Lymphoma" from: Cope-Working in Oncology, Mar./Apr. 1994.
 Sally J. DeNardo et al. "The Biologic Window for Chimeric 1.6 Radioimmunotherapy", *Cancer Supplement*, vol. 73, No. 3, pp. 1023-1032. Feb. 1, 1994.

Mitchell E. Reff, "Depletion of B Cells In Vivo by a Chimeric Mouse Human Monoclonal Antibody to CD20", *Blood*, vol. 83, No. 2, pp. 435-445, Jan. 15, 1994.
Genetic Engineering News, "Developing Chimeric Monoclonals", vol. 5, No. 3, Mar. 1985.

Liu et al., "Production of a Mouse-Human Chimeric Monoclonal Antibody to DCD20 With Potent FC-Dependent Biologic Activity", *Journal of Immunology*, vol. 139, No. 10, 15 Nov. 1987, pp. 3521-3526.

Hekman et al., "Immunotherapy", *The Netherlands Cancer Institute Amsterdam Annual Report* 1993, pp. 47-48.

Reff et al., "Depletion of B Cells in Vivo by a Chimeric Mouse Human Monoclonal Antibody to CD20", *Journal of Cellular Biochemistry*, vol. 17, No. Supplement 17E, 29 Mar. 1993, p. 260.

Anderson, D.R. *The Second Annual IBC International Conference on Antibody Engineering*, Dec. 16-18, 1991. Press, O.W. 69/2 *Blood* 584 (1987).

Robinson, R.R. *2 Hum. Antibod. Hybrid.* 84 (1991).

Morrison, S.L. 81 *PNAS* 6851 (1984).

Boulianne, G.L. 312 *Nature* 643 (1984).

Neubeiger, M.D. 314 *Nature* 268 (1985).

Tan, L.K. 135 *J. Immunol.* 8564 (1985).

Sun, L.K. 5/1 *Hybridoma* 517 (1986).

Sahagan, B.G. 137 *J. Immunol.* 1066 (1986).

Munro, A. 312 *Nature* 597 (1984).

Marx 229 *Science* 455 (1985).

Morrison 229 *Science* 1202 (1985).

Grossbard, M.L. 80/4 *Blood* 863 (1992).

Clark, E. 82 *PNAS* 1766 (1985).

Robertson, M.J. 79/9 *Blood* 2229 (1992).

Nadler, L.M. *The Lancet* 427 (Aug. 25, 1984).

Golay, J.T. 135/6 *J. Immunol.* 3795 (1985).

Greenberger, J.S. 45 *Can. Res.* 758 (1985).

Nadler, L.M. 40 *Can. Res.* 3147 (1980).

Tedder, T.F. 141/12 *J. Immunol.* 4388 (1988).

Einfeld, D.A. 7/3 *The EMBO Journal* 711 (1988).

Tedder, T.F. 135/2 *J. Immunol.* 973 (1985).

Tedder, T.F. 16 *Eur. J. Immunol.* 881 (1986).

Valentine, M.A. 264/19 *J. Bio. Chem.* 11282 (1989).

Ozato, K. 126/1 *J. Immunol.* 317 (1981).

Calvert, J.E. 21/4 *Sem. Hema.* 226 (1984).

Anderson, K.C. 63/6 *Blood* 1424 (1984).

Oettgen, H.C. 2/1 *Hybridoma* 17 (1983).

Lipton, J.M. 60/1 *Blood* 170a (Abs. 609) (1982).

Anderson, K.C. 69/2 *Blood* 597 (1987).

Adams, R.A. 27/1 *Can. Res.* 2479 (1967).

Adams, R.A. 28 *Can. Res.* 1121 (1968).

Smeland, E.B. 138/10 *J. Immunol.* 3179 (1987).

Nadler, L.M. 74 *J. Clin. Invest.* 332 (1984).

(List continued on next page.)

Primary Examiner—Ronald B. Schwadron

Attorney, Agent, or Firm—Burns, Doane, Swecker & Mathis, LLP

[57]

ABSTRACT

Disclosed herein are therapeutic treatment protocols designed for the treatment of B cell lymphoma. These protocols are based upon therapeutic strategies which include the use of administration of immunologically active mouse/human chimeric anti-CD20 antibodies, radiolabeled anti-CD20 antibodies, and cooperative strategies comprising the use of chimeric anti-CD20 antibodies and radiolabeled anti-CD20 antibodies.

6 Claims, 21 Drawing Sheets